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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/376,487 | 08/18/1999 | AWADHESH K. MISHRA | 402090/SKYE PHARMA | 6585 |
| 21874 | 7590 | 07/12/2004 | EXAMINER | |
| EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205 | | | WEBMAN, EDWARD J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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6/12/04

DATE MAILED:

This is a communication from the examiner in charge of your application.
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OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4/1/04

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 48-150 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 48-61, 63-67, 69-85, 89-93, 100-122, 129-136 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3/26/01, 12/4/02, 12/10/02, 12/17/02

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45-61, 63-67, 69-85, 89-93, 100-123, 129-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPA 770387 (EPA '387).

EPA '387 teaches a composition comprising 0.1-2% central acting anesthetic, 5-30% long chain and/or medium chain triglycerides, and 0.5-2% emulsifier (abstract). Olive oil is disclosed (column 3 line 34). Lecithin is specified (column 3 line 48). A ratio of 10:-1:10 long to medium chain triglycerides is specified (column 3 lines 49-50). Mannitol is disclosed as a tonicity agent (column 4 line 26). A droplet size of 0.2-0.35 μm is specified (column 5 line 2). Long term stable emulsions are disclosed (column 3 line 9).

The examiner takes notice under MPEP 2144.03 that propofol is well-known in the art as a central acting anesthetic.

It would have been obvious to one of ordinary skill to deliver propofol, well-known in the art as a central acting anesthetic, in the vehicle of EPA '387 to achieve the beneficial effect of long term stability. As to the claimed mannitol concentration, no criticality has been shown. As to the claimed nitrogen, and PH such would be obvious expedients to prevent oxidation in the oil phase and achieve physiological compatibility respectively.

Art Unit: 1617


Claims 62, 68, 86-88, 94-99, 123-128 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 137-150 allowed.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.

Webman/tgd

June 15, 2004



EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500